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09/607,602	06/30/2000	Matthew Joseph Doyle	8141	8543

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EXAMINER
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NOLAN, PATRICK J

ART UNIT	PAPER NUMBER
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**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

Paper No. 040204

Application Number: 09/607,602  
Filing Date: June 30, 2000  
Appellant(s): DOYLE ET AL.

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Emelyn L Hilland  
For Appellant

**EXAMINER'S ANSWER**

This is in response to the appeal brief filed 1-20-04.

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A statement identifying the real party in interest is contained in the brief.

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief. It is noted that the related appeal, 09/607, 240, was adjudicated by B.P.A.I., in which the Examiner's Final rejection was affirmed.

The statement of the status of the claims contained in the brief is correct.

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

The summary of invention contained in the brief is correct.

The appellant's statement of the issues in the brief is correct.

The rejection of claims 2-4 and 7 stand or fall together because appellant's brief does not include a statement that this grouping of claims does not stand or fall together and reasons in support thereof. See 37 CFR 1.192(c)(7).

The copy of the appealed claims contained in the Appendix to the brief is correct.

WO 97/16159	Pan et al.
5,346,616	Singer et al.
JP 04089428A	Tsujita et al.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 2-4 and 7 stand rejected under 35 U.S.C. 102(b) as being anticipated by Pan et al (WO 97/16159).

Pan et al teaches that histamine H-2 receptor antagonists including cimetidine may be employed in an oral composition in an amount effective to treat or prevent inflammations in the oral cavity said composition may also comprise essential oils to act as antimicrobial agents. Therefore the referenced teachings anticipate the claimed invention. It is noted that the whole body health benefits are inherent in the referenced methods. Newly discovered results of known processes directed to the same purpose are not patentable because such results are inherent. See MPEP 2112- 2112.02. Also, see Ex parte Novitski 26 USPQ 1389 (BPAI 1993)', Mehl/Biophile International Corn. V. Milgraum, 52 USPQZd 1303 (Fed. Cir. 1999). Atlas Powder Co.V. IRECO, 51 USPQZd 1943 (Fed. Cir. 1999). Preamble language In claims of patents directed to administration of anticancer drugs are expressions of purposes and intended results, and as such are non-limiting, since language does not result in manipulative difference in steps of claims. The instant case does not present a situation in which the new use of a process should be considered limiting because it distinguishes process over prior art (Bristol Myers Squibb Company v. Ben Venue Laboratories 58 USPQZd 1508 (CAFC 2001), previously 00-1304 (CAFC 4/20/01).

Therefore, the referenced teachings anticipate the claimed invention.

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Claims 2-4 and 7 stand rejected under 35 U.S.C. 102(b) as being anticipated by Singer et al (U.S. No. 5,364,616).

The '616 patent teaches a method for treatment and prevention of gingivitis or periodontitis comprising the topical administration of the oral cavity of a composition comprising a histamine-z receptor antagonist compound in the form of a dentifrice, mouthwash, mouth rinse, mouth spray, or dental treatment solution (see entire patent especially the abstract and claims 1-8 and column 21, lines 5-18). The '616 patent also teaches that the compositions used said methods can be in the form of a toothpaste, tooth gels, tooth powders, chewing gum, which may act as odor masking agents (see entire patent especially column 15, lines 24-60, and claims 9-15). The '616 patent also teaches that the compositions used in said methods can be a non-abrasive gel as disclosed in column 16 lines 5-12, which teaches silica gels that do not abrade dentin. The '616 patent also teaches that the compositions used in said methods can be a dental implement such as a control release delivery system as taught in column 20, lines 44-65, and can be comprised of cellulose hollow fibers (column 16, lines 46-50) which is consistent with the definition of a dental implement disclosed on page 30, lines 17-18 of the instant application. The '616 patent also teaches that the compositions used in said methods can encompass antimicrobial/anti-plaque agents which include antibiotics (column 18, lines 48-51), bio-film inhibiting agents such as surfactant (column 17, lines 46-62), and analgesics such as aspirin (column 19 lines 10-17). It is noted that the whole body health benefits are inherent in the referenced methods. Newly discovered results of known processes directed to the same purpose are not patentable because such results are inherent. See MPEP 2112-2112.02. Also, see Ex Parte Novitski 26 USPQ 1389 (BPAI 1993), Mehl/Biophile International Corp. V. Milgraum, 52 USPQ2d 1303 (Fed. Cir.

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1999); Atlas Powder Co. V. IRECO, 51 USPQ2d 1943 (Fed. Cir. 1999). Preamble language in claims of patents directed to administration of anticancer drugs are expressions of purposes and intended results, and as such are non-limiting, since language does not result in manipulative difference in steps of claims. The instant case does not present a situation in which the new use of a process should be considered limiting because it distinguishes process over prior art (Bristol Myers Squibb Company v. Ben Venue Laboratories 58 USPQ2d 1508 (CAFC 2001), previously 00- 1304 (CAFC 4/20/01)).

Therefore, the referenced teachings anticipate the claimed invention.

Claim 2 stands rejected under 35 U.S.C. 102(b) as being anticipated by Tsujita et al (JP 04089428A).

Tsujita et al teaches a method of treating the oral cavity disease of gingivitis comprising cimetidine as an active ingredient (see abstract only, since the rest of the patent is in Japanese). It is noted that the whole body health benefits are inherent in the referenced methods. Newly discovered results of known processes directed to the same purpose are not patentable because such results are inherent. See MPEP 2112- 2112.02. Also, see Ex parte Novitski 26 USPQ 1389 (BPAI 1993)., Mehl/Biophile International Corp. V. Milgraum, 52 USPQ2d 1303 (Fed. Cir. 1999)', Atlas Powder Co. V. IRECO, 51 USPQ2d 1943 (Fed. Cir. 1999). Preamble language in claims of patents directed to administration of anticancer drugs are expressions of purposes and intended results, and as such are non-limiting, since language does not result in manipulative difference in steps of claims. The instant case does not present a situation in which the new use

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of a process should be considered limiting because it distinguishes process over prior art (Bristol Myers Squibb Company v. Ben Venue Laboratories 58 USPQ2d 1508 (CAFC 2001), previously 00-1304 (CAFC 4/20/01).

Therefore, the referenced teachings anticipate the claimed invention.

Response to Argument:

Appellant argues that rejection of the present claims is improper because none of the citations discloses all the material elements of the claims. None of the citations disclose the "new use" of the present method to promote whole body or systemic health. Appellant cites *In re Marshall* 578 F.2d 301, 198 USPQ 344 (CCPA), to support their position.

However, the Examiner's position is that the claimed invention is not a new use of an old process but is an unrealized benefit of an old process. The old process is indistinguishable from the presently recited claims in either the patients treated, active agents used or mode of administration and/or dosage amount used.

Appellant argues their claimed invention is distinguishable from *Bristol-Myers Squibb v. Ben Venue Laboratories* 58 USPQ 2d 1508 (CAFC 246 F.3d 1368 2001), because in that the present "use" is not known nor suggested by the prior art and is therefore a new use, while the use in *Bristol*, i.e. "treating cancer by administering paclitaxel" is the same use as disclosed in the prior art, that of treating cancer. However, the examiner notes that the claimed method of "promoting whole body health" in the instant case is an extension of the method taught by the prior art references because the claimed method of promotion of whole body health is a direct result of the antimicrobial effect on oral pathogens mediated by administration of a composition

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comprising the same ingredients, in the same concentrations, and administered by the same route as that taught by the prior art.

Appellant further contends on page 9 of the Brief that the present case is different from the *In re Woodruff* because the claimed method was directed to the same use and not to a new use or purpose. In *Woodruff* the claimed use to inhibit the visible growth of fungi on refrigerated fruits and vegetables was found to be generically encompassed by the prior art which is directed to a method of storing fresh and leafy vegetables in a modified atmosphere and at a lower temperature in order to maintain a fresh appearance. Appellant states that *Woodruff's* method is therefore not directed to a new use or purpose, but simply a more specific benefit of inhibiting the visible growth of fungi. However, the Examiner notes that if *Woodruff's* method of inhibiting the growth of fungi is considered to be directed to the same use as the method of the prior art which is directed to a method of storing fresh and leafy vegetables in a modified atmosphere and at a lower temperature, and is not directed to a new use or purpose, then *Woodruff's* method is thus is a result or extension of the prior art's method of storing fresh and leafy vegetables in a modified atmosphere and at a lower temperature, because the method of the prior art is also is mediated by inhibiting the visible growth of fungi. Similarly, the systemic benefits of the instantly claimed methods of promoting whole body health is not directed to a new use over the method of treatment of the localized oral disorders of gingivitis, periodontitis and dental plaque taught by the prior art because said claimed systemic benefits are mediated by the antimicrobial mechanism of action of said compositions and thus the instantly claimed method of promoting whole body health is a result or extension of the prior art's method of



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treatment of the localized oral disorders of gingivitis, periodontitis and dental plaque taught by the prior art references.

Appellant further contends on page 9 of the Brief that the present case is different from the *Verdegaal Bros., Inc v Union Oil* because the claimed method was directed to the same use and not to a new use or purpose. However as stated in the previous paragraph, it is the Examiner's position that the systemic benefits of the instantly claimed methods are an extension of the method of treatment of the localized oral disorders of gingivitis, periodontitis and dental plaque taught by the prior art references, for the reasons discussed supra.

Appellant further contends on page 10 of the Brief that the present case is different from the *Bird Provision Co v Owens Country Sausage, Inc* because the claimed use in Bird is not a new use, and that though the public did not understand or appreciate the shelf life implications of the process of producing and preserving fresh pork sausage. Similarly, the Examiner contends that the instant claims encompass a use that was inherent to the methods taught by the prior art references, despite the lack of appreciation of the systemic effects of the known process of treatment of the localized oral disorders of gingivitis, periodontitis and dental plaque taught by the prior art references.

Appellant further contends on page 10 of the Brief that the present claimed methods involving topically administering a composition comprising an antimicrobial agent and an H2-antagonist has new and unobvious beneficial effects and are therefore patentable as a new use of a process even if the process were known. In support of said position, Appellant presents on page 11 of said brief that in *In re Shetty* the CCPA reversed an obviousness rejection. However the Examiner notes that the present rejection is a 102 anticipation rejection, not a 103

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obviousness rejection, and as such does not apply instantly. Also in support of said position, Appellant presents on pages 11-12 of the Brief that in *In re Marshall* claims directed to a method of controlling weight using oxethazaine was not anticipated by art which taught that oxethazain was used to treat digestive diseases such as esophagitis, gastritis. The Examiner notes that in *Marshall* the method of controlling weight was not a direct result or extension of the successful treatment of digestive disease. However, unlike *Marshall*, the method encompassed by the instantly recited claims is an extension of the methods taught by the prior art references mediated by the local antimicrobial mechanism which confers the claimed systemic effects of whole body health, and as such is not an accidental or unwitting duplication of an invention which the CCPA stated can not constitute an anticipation.

Appellants further contend on page 12 of the Brief that the Examiner has not provided evidence that one of ordinary skill in the art would recognize the new use of the present claimed method, i.e. promoting systemic or whole body health. However, the examiner notes that one of ordinary skill in the art would recognize that the method of the prior art references would reduce the quantity of oral pathogens in the oral cavity, and that this in turn would reduce the quantity of pathogens entering the bloodstream from the gums. The examiner notes that one of ordinary skill in the art would recognize that reduction of said pathogens in the blood would promote systemic or whole body health.

Appellants further contend on pages 13-14 of the Brief, that a second or new medicinal use of a substance is patentable as a method of use. Appellant cites US Patent 6,100,270, which involves the oral administration of sildenafil compositions for a second medicinal use, though said compositions had been previously patented for the treatment of various other conditions.

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However, the Examiner notes that the dosages of the substance administered for each of the conditions was not identical in the various patents. Appellant also cites that methods of treating male pattern baldness by the topical administration of minoxidil were patented as a second medicinal use, and that a previous patented use was for a method of treating hypertension. However, the Examiner notes that the method of treating male pattern baldness by the topical administration of minoxidil is not a direct extension of the method of treating hypertension because of their divergent mechanisms of action in different patient populations, and is therefore not analogous to the instant application.

On page 14 of the Brief, Appellant disagrees with the Examiner's contention that, unlike the present case in which the claimed methods are applied to the same patient population, the methods in the cases of patented second medicinal uses are applied to various distinct patient populations. Appellant states that the present claimed methods are for use in all subjects, regardless of their need for treatment of dental plaque, gingivitis or periodontitis. However the Examiner notes that the methods disclosed by the prior art are not limited to subjects with need for treatment of dental plaque, gingivitis or periodontitis, because Claim 1 of Singer et al recites a method of preventing of dental plaque, gingivitis or periodontitis, which would apply for all subjects. Furthermore, since the presently appealed claims encompass ALL subjects, the subjects treated in the prior art references would be a species to the genus of any patient population and therefore still anticipate.

Accordingly, it is the position of the Examiner that though Appellant is claiming a new benefit (whole body health) of an old process (topical administration to the oral cavity of an antimicrobial agent optionally with an H2 antagonist), the method of promoting whole body

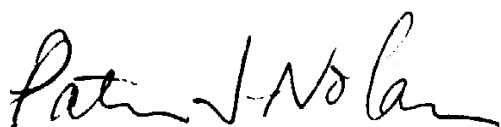
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health defined by instant Claims 2 and 4-7 is not patentably distinct from WO 97/16159 to Pan et al., 5,346,616 to Singer et al., and JP 04089428A to Tsujita et al., for the reasons discussed above.

Therefore the rejection of instant claims 2-4 and 7 under 102(b) as being anticipated Pan et al., Singer et al., and over claim 2 by Tsujita et al., is proper.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,




Patrick Nolan, Ph.D.  
Primary Examiner, TC 1600  
April 2, 2004

Conferees

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